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APPLICATION NUMBER: 60/549,317

FILING DATE: *March 02, 2004*

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17157 U.S. PTO
030204

PTO/SB/16 (08-03)

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

Express Mail Label No.: EV373505232US

INVENTOR(S)					
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Bradley William Elias		KOEPEL CONWAY		Smyrna, GA Smyrna, GA	
<input checked="" type="checkbox"/> Additional inventors are being named on the 1 separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
"MINIATURE, MULTI-USE MICRO-SAMPLING DEVICE"					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number 23506					
OR					
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ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages		13		<input type="checkbox"/> CD(s), Number	
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets		9		<input checked="" type="checkbox"/> Other (specify) Return Postcard	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.					
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees					
<input checked="" type="checkbox"/> The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 50-1513					
<input checked="" type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
FILING FEE AMOUNT (\$) \$160					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

15535 U.S. PTO
60/549317

030204

[Page 1 of 2]

Respectfully submitted,

SIGNATURE



Date

03/02/04

TYPED or PRINTED NAME

Bradley K. Groff

REGISTRATION NO.

39,695

(if appropriate)

Docket Number:

2G02.1-190

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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Docket Number		2G02.1-190
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Number 1 of 1

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R. Hall

PROVISIONAL
APPLICATION FOR LETTERS PATENT
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Be it known that **Bradley KOEPPPEL**, of 102 Vinings Parkway SE, Smyrna, GA 30080; **William Elias CONWAY**, of 1609 Countryside Place, Smyrna, GA 30080; **Brian VANHIEL**, of 3993 Plumcrest Circle, Smyrna, GA 30082; **Jack GRIFFIS**, of 1133 Druid Lake, Decatur, GA 30033; and **David BUENGER**, of 4171 Edinburgh Trail, Roswell, GA 30075, all citizens of the United States of America, have invented certain new and useful improvements in a

MINIATURE, MULTI-USE MICRO-SAMPLING DEVICE

for which the following is a specification.

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MINIATURE, MULTI-USE MICRO-SAMPLING DEVICE

Technical Field

[0001] The present invention relates generally to medical devices and procedures, and more particularly to a multi-use, micro-sampling device.

Background of the Invention

[0002] Many medical procedures require puncturing of the skin, and sometimes underlying tissues, of an animal or human subject. For example, a sharp lancet tip is commonly used to puncture the subject's skin at a lancing site to obtain a sample of blood, interstitial fluid or other body fluid, as for example in blood glucose monitoring by diabetics and in blood typing and screening applications.

[0003] In some instances, a person must periodically sample their blood for multiple testing throughout the day or week. Thus, due to the nature of micro-sampling for blood glucose monitoring, many individuals requiring regular monitoring prefer to do so discretely. Current multi-use micro-sampling devices tend to have a large, pen-like form that restricts the ability of the individual user to conduct micro-sampling discretely. Some have attempted to miniaturize the micro-sampling device, but the device still has a large and indiscrete size.

[0004] Thus it can be seen that needs exist for improvements to lancing devices to provide a micro-sampling device having a small and discrete size. Needs further exist for such a mechanism that has a smaller overall profile while remaining compatible with standard lancets commonly available. In addition, needs exist for combining drive elements for control of the lancet travel and return that provide for a wide, yet far shorter overall design.

Summary of the Invention

[0005] Briefly described in example forms, the present invention is a multi-use micro-sampling or lancing device comprising a compact outer housing containing drive and activation mechanisms for receiving a disposable and replaceable lancet, and driving the lancet through a controlled lancing stroke for sample collection. The housing preferably includes a lancet holder that securely but releasably engages the lancet and constrains the lancet along a controlled and pre-defined path of travel during the lancing stroke.

[0006] The lancing device preferably includes a drive mechanism including a pair of opposed torsion springs working in tandem to drive and propel the lancet through an extended position along its lancing stroke, and to return the lancet to a retracted position fully within the housing. This drive mechanism is compact, and thus, the overall size, and particularly the length, of the lancing device can be significantly reduced. The lancing device may, for example, have the overall size and shape of a typical automotive door-lock remote control keyfob.

[0007] These and other aspects, features and advantages of the invention will be understood with reference to the drawing figures and detailed description herein, and will be realized by means of the various elements and combinations particularly pointed out in the appended claims. It is to be understood that both the foregoing general description and the following brief description of the drawings and detailed description of the invention are exemplary and explanatory of preferred embodiments of the invention, and are not restrictive of the invention, as claimed.

Brief Description of the Drawings

[0008] **FIGURE 1** is an assembly view of a multi-use lancing device according to an example embodiment of the present invention.

[0009] **FIGURE 2** is a top sectional view of a lancet holder component of the multi-use lancing device of **FIGURE 1**.

[0010] **FIGURE 3** is a top sectional view of the multi-use lancing device of **FIGURE 1** prior to the insertion of a lancet, and with the endcap removed.

[0011] **FIGURE 4** is a top sectional view of the multi-use lancing device of **FIGURE 1** having a lancet inserted therein, and with the drive mechanism in its extended “ready” configuration.

[0012] **FIGURE 5** is a detailed view of interengaging locking elements of the lancet holder of **FIGURE 4**.

[0013] **FIGURE 6** is a top sectional view of the multi-use lancing device of **FIGURE 1** having the lancet inserted therein, with its protective sterility cap removed.

[0014] **FIGURE 7** is a top sectional view of the multi-use lancing device of **FIGURE 1**, with its endcap portion attached and having a lancet in the ready position.

[0015] **FIGURE 8** is a top sectional view of the multi-use lancing device of **FIGURE 1**, as the device is activated to release the drive mechanism from its ready state.

[0016] **FIGURE 9** is a top sectional view of the multi-use lancing device of **FIGURE 1**, with the lancet in its extended position wherein the lancet tip projects outwardly from the device’s housing.

[0017] **FIGURE 10** is a top sectional view of the multi-use lancing device of **FIGURE 1**, with the used lancet withdrawn back into its retracted position with the sharp lancet tip fully enclosed within the housing.

[0018] **FIGURE 11** is a top sectional view of a multi-use lancing device according to another example embodiment of the present invention, with a different drive and return spring configuration.

Detailed Description of Example Embodiments

[0019] The present invention may be understood more readily by reference to the following detailed description of the invention taken in connection with the accompanying drawing figures, which form a part of this disclosure. It is to be understood that this invention is not limited to the specific devices, methods, conditions or parameters described and/or shown herein, and that the terminology used herein is for the purpose of describing particular embodiments by way of example only and is not intended to be limiting of the claimed invention. Also, as used in the specification including the appended claims, the singular forms "a," "an," and "the" include the plural, and reference to a particular numerical value includes at least that particular value, unless the context clearly dictates otherwise. Ranges may be expressed herein as from "about" or "approximately" one particular value and/or to "about" or "approximately" another particular value. When such a range is expressed, another embodiment includes from the one particular value and/or to the other particular value. Similarly, when values are expressed as approximations, by use of the antecedent "about," it will be understood that the particular value forms another embodiment.

[0020] With reference now to the drawing figures, **FIGURE 1** is an assembly view of a multi-use micro-sampling device or lancing device 10 according to an example embodiment of the present invention. The lancing device 10 preferably comprises a housing 11 having a top portion 12b connected to a bottom portion 12a, as by adhesive or crush-pins. An endcap portion 25 of the lancing device 10 is removably connected to the housing 11 such that a new lancet can be manually inserted into the device and a used lancet can be manually removed from the device. The endcap portion 25 preferably defines an opening 27 for protrusion of a sharp lancet needle or tip into the tissue at the intended lancing site selected by user. At the end of the housing 11 opposite the endcap portion 25 is an opening 18 for receiving an activating button assembly 20.

[0021] Within the housing 11, a replacable and disposable lancet 5 is installed in a reciprocating lancet holder 30. The lancet 5 typically comprises a needle or blade forming a sharp lancet tip 7 and a lancet body 6, and is positioned such that the tip 7 is directed forward, toward the lancet opening in the endcap portion 25. Preferably, the lancet body 6 is formed of plastic, and is injection-molded around the needle or blade. The lancet tip 7 is preferably encapsulated by a protective sterility cap 15, which is integrally molded with the lancet body 6, and forms a sterility and safety barrier for the lancet tip 7. As shown in **FIGURE 1**, the protective sterility cap 15 of each lancet 5 is releasably connected to the body 6 at a transition region 9, which is an area of weakening such that it is easily detached and removed from the lancet body 6. The lancet 5 can be, for example, a standard, commercially-available lancet such as an Accu-Check® Softclix® lancet.

[0022] As more clearly seen in **FIGURE 2**, the lancet holder 30 preferably comprises male guidance features 32 and an opening 37. The male guidance features 32 are integrated onto both the upper and lower surfaces of the lancet holder 30, and slide within interengaging female features such as grooves 19 in the upper and lower portions 12a and 12b of the housing, to constrain the lancet along a controlled and pre-defined path of travel during the lancing stroke. The opening 37 is sized and shaped to securely but releasably hold the replacable lancet.

[0023] The lancet holder 30 preferably has a generally U-shaped portion 31 formed by an opposed pair of compression arms 36, with chamfered barbs 33 for engaging co-acting retaining tabs 16 integrated within the bottom portion 12a of the housing 11. The retaining tabs 16 engage the barbs 33 to maintain lancet holder 30 in a “ready” position against the bias force of the drive spring when the device is cocked. The ends of the retaining tabs 16 preferably define a chamfer for sliding contact along the cooperating chamfered faces 35 of the barbs 33, to provide a smooth cocking action. The compression arms 36 can resiliently flex inwardly and thus allow movement of their free ends towards each other upon cocking and firing of the device. The barbs 33 have flat edges 34 for releasable engagement against the retaining tabs 16 in the ready position.

[0024] The lancing device 10 preferably further comprises a drive mechanism, seen best with reference to **FIGURES 3, 4, 6, 7, 8, 9, and 10**. Two torsion springs, namely a drive spring 55 and a return spring 53, operate in tandem to drive and return the lancet holder 30 along the lancing stroke upon activation of the lancing device 10. The drive spring 55 is the stronger of the two springs and drives the lancet from its initial position into its extended position. The return spring 53 serves to retract the lancet back into the housing after lancing the skin. A pair of posts or lugs 51a and 51b serve as retainers for positioning the springs 53 and 55, and thereby more precisely defining the equilibrium position of the lancet holder 30. The springs 53 and 55 are secured within the housing 11 around a pair of torsion spring orientation features 13 projecting from the bottom portion 12 of the housing 11.

[0025] The lancing device 10 preferably further comprises the activating button assembly 20 positioned at the end of the housing 11 opposite the endcap portion 25, for activating the drive mechanism to propel the lancet through its lancing stroke. An example configuration of the activating button assembly 20 preferably includes a button portion 40 having a pair of posts 42 which contact the chamfered faces 35 of the compression arms 36 of the lancet holder 30, pressing the arms 36 inwardly to release the flat edges 34 of barbs 33 from engagement with the retaining tabs 16 to initiate the lancing action when the button 40 is pressed by the user. The activating button assembly 20 preferably further comprises a coil spring 57, which abuts against a post 17 extending from the housing, for biasing the button 40 outwardly.

[0026] The opposed, tandem torsion spring drive mechanism permits a significant reduction in the overall size of the lancing device 10, as compared to typical known lancing devices. Thus, the overall size of the lancing device 10 may be a bit wider than conventional lancing devices, but the length of the device 10 is much shorter. With this reduced size, the lancing device 10 can accommodate other features, such as an

adjustable depth-control ring, a lancet storage feature, or other similar optional features, without resulting in an objectionably large device.

[0027] **FIGURE 3** shows a top view of the multi-use lancing device 10 prior to the insertion of the lancet 5. The lancet holder 30 is unloaded, and thus the lancet holder 30 is considered to be in a “withdrawn” or “steady” state. In this “withdrawn” state, the activating button 40 and the spring arm 57 are fully retracted. Thus, the spring 57 is positioned against the stop feature 17 of the bottom portion 12a. The return torsion spring 53 is in a retracted compression state, or its “equilibrium” or “steady” state, and opposes the “equilibrium” or “steady” position of the drive spring 55. The drive torsion spring 55 is also in a forward compression state, or its “steady” compression state. In this position, the drive spring 55 and return spring 53 counter-balance one another, and the lancet holder 30 is in an equilibrium position.

[0028] When the device is in its “equilibrium” state, a user manually loads a lancet into the lancet holder 30 and pushes the lancet holder back, until the barbs 33 of the lancet holder snap into engagement with the lancet holder cocking tabs 16, thereby placing the device in its “cocked” or “ready” position.

[0029] **FIGURE 4** shows the lancing device 10 without the endcap portion 25 and having a lancet 5 inserted therein. The lancet 5 is shown with its protective cap 15 still connected to its body 6. The return torsion spring 53 is in its non-compressed or “relaxed” state, and the drive torsion spring 55 is in its fully –extended or “ready” state. Thus, a biasing force is applied by the extended drive spring 55 on the lancet holder 30 in the forward direction (i.e., toward the lancet tip). The activating button assembly 20 is in its “steady” state. **FIGURE 5** is a detailed view of the flat edges 34 of the barbs 33 in engagement with the locking tabs 16, holding the drive mechanism in its cocked or “ready” state. The user manually removes the protective sterility cap 15 from the lancet body prior to replacing the endcap 25.

[0030] **FIGURE 6** shows the multi-use lancing device 10 having the lancet 5 inserted therein and with its protective sterility cap 15 manually removed, thereby exposing the lancet tip 7. Once the protective sterility cap 15 has been removed, the user then replaces the endcap portion 15. **FIGURE 7** shows the lancing device 10 with its endcap portion 25 in place. The user then places the opening 27 of the lancing device 10 against his or her skin at the desired lancing site, and presses the button to fire or “activate” the lancing device.

[0031] **FIGURE 8** shows the lancing device 10 as the device is being triggered or “activated”. The lancing device 10 is activated when the activating button assembly 20 is pressed. As the button is pressed, the opening 18 in the housing guides the movement of the activating button 40 during compression of the spring 57. Posts 42 engage the chamfered faces 35 of the compression arms 36 of the lancet holder 30, to flex the arms inwardly and release the barbs 33 from tabs 16, initiating the lancing action. Because the drive spring 55 is stiffer than the return spring 53, the lancet is driven forward into its extended position. The lancet moves into its extended position, wherein its tip punctures the user’s skin at the lancing site, and then is withdrawn back to a retracted position where the lancet tip 7 is shielded within the housing 11.

[0032] **FIGURE 9** shows the lancing device 10 with the lancet tip 7 in its extended position, projecting through the opening 27 of the endcap portion 25. The lancet 5 and the lancet holder 30 are in their fully extended positions when the forward face of the lancet body contacts an inner surface 19 of the endcap portion 25. In alternate embodiments, the endcap 25 optionally includes a depth adjustment mechanism (unshown) permitting the user to selectively vary the position of the stop surface 19. Upon release of the activating button assembly 20 the retraction spring 57 biases the activating button back to its initial position. The return torsion spring 53 is extended, and the drive spring 55 is relaxed, thereby imparting a force to bias the lancet holder back toward its withdrawn position. Once the lancing procedure is completed, the tip of the lancet is drawn back into the

lancing device, and the user removes the lancing device from the lancing site so as to obtain a sampling of blood or other bodily fluid.

[0033] **FIGURE 10** shows the multi-use lancing device 10 with the used lancet 5 drawn back into its withdrawn position, fully within the housing. The springs 53 and 55 have returned to their equilibrium or “steady” state. The endcap portion 25 of the lancing device 10 can now be detached so that the used lancet can be removed and a new lancet can be inserted. As seen in **FIGURE 9**, the activating button assembly 20 including the retraction spring 57 has returned to its “steady” state such that the activating button 40 is fully retracted.

[0034] **FIGURE 11** shows a multi-use lancing device 10' according to another example embodiment of the present invention. The lancing device 10' is substantially similar to the lancing device 10 with the exception of the orientations of the drive torsion spring 55' and return torsion spring 53'. The lancet holder 30' is shown in its “steady” state, with springs 53' and 55' in equilibrium. When the device is cocked to place the lancet holder in the ready position, the drive spring 55' is compressed to apply force on the lancet holder in the forward direction, and the return spring 53 is relaxed. When the device is activated to release the lancet holder and the lancet moves to its extended position, the return spring 53 is compressed to apply rearward force on the lancet holder 30, and the drive spring 55 is relaxed. The springs 53', 55' then return to equilibrium with the lancet holder 30 back in its retracted position within the housing. Thus, in the device of Fig. 11, the energized states of the drive torsion spring 55' and the return torsion spring 53' are compressed in the “coil” directions to provide biasing force on the lancet holder; whereas in Figures 1-10, the energized states of the springs 53 and 55 are extended in the “reverse coil” directions. A pair of posts or lugs 51a' and 51b' serve as retainers to position the springs 53' and 55', and thereby more precisely define the equilibrium position of the lancet holder 30'.

[0035] While the invention has been described with reference to preferred and example embodiments, it will be understood by those skilled in the art that a variety of modifications, additions and deletions are within the scope of the invention, as defined by the following claims.

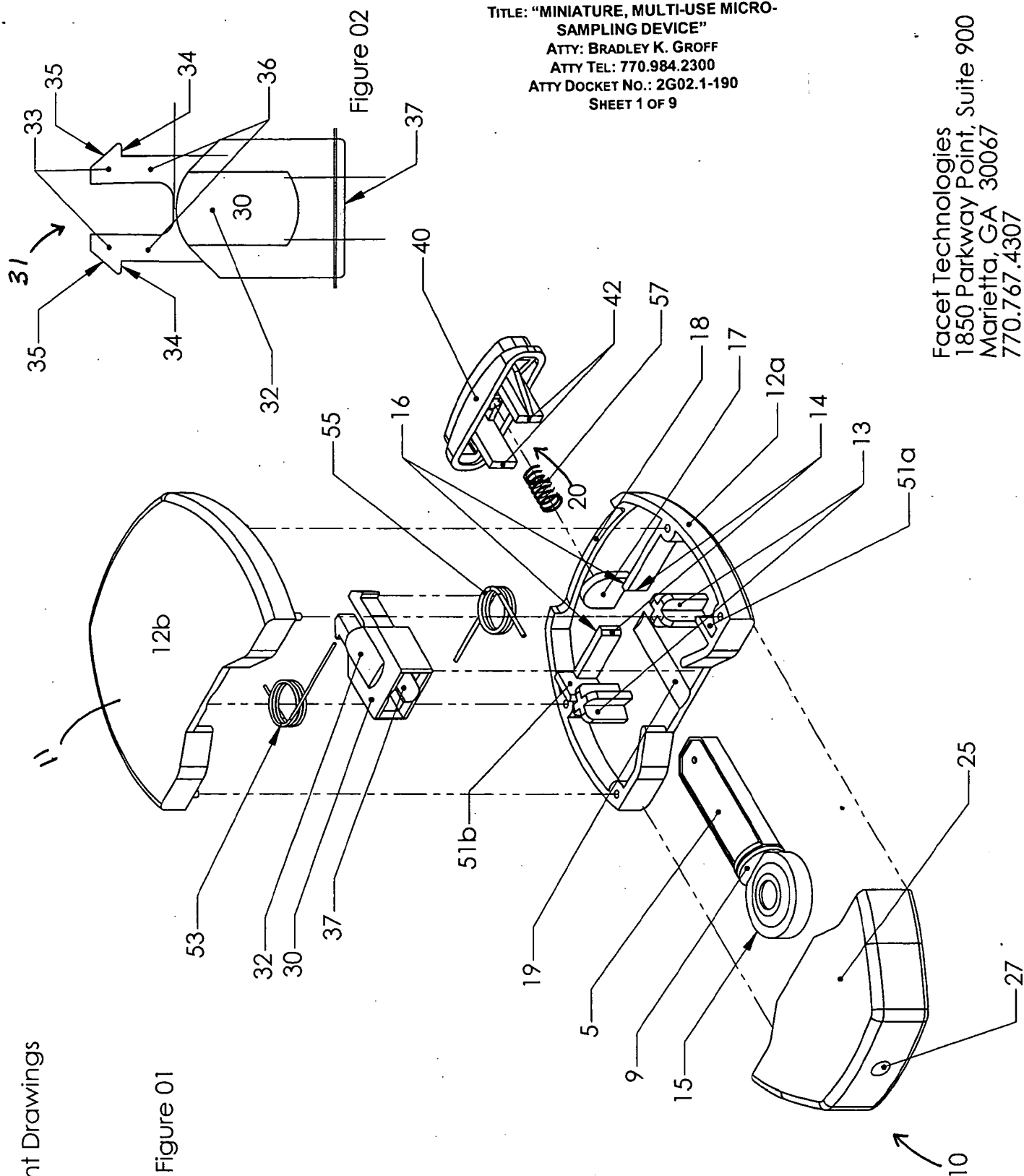
CLAIMS

What is claimed is:

1. A lancing device comprising:
a housing;
a lancet holder for holding a lancet translationally mounted within the housing; and
a drive mechanism comprising a pair of opposed torsion springs working in tandem to drive and return the lancet holder along a lancing stroke.
2. The lancing device of Claim 1, wherein the housing further comprises a detachable endcap portion.
3. The lancing device of Claim 1, further comprising an activating mechanism to release the drive mechanism to traverse the lancing stroke.
4. The lancing device of Claim 3, wherein the lancet holder has at least one chamfered barb, and wherein the activating button comprises a post for contacting the chamfered barb to release the activating mechanism.

ABSTRACT

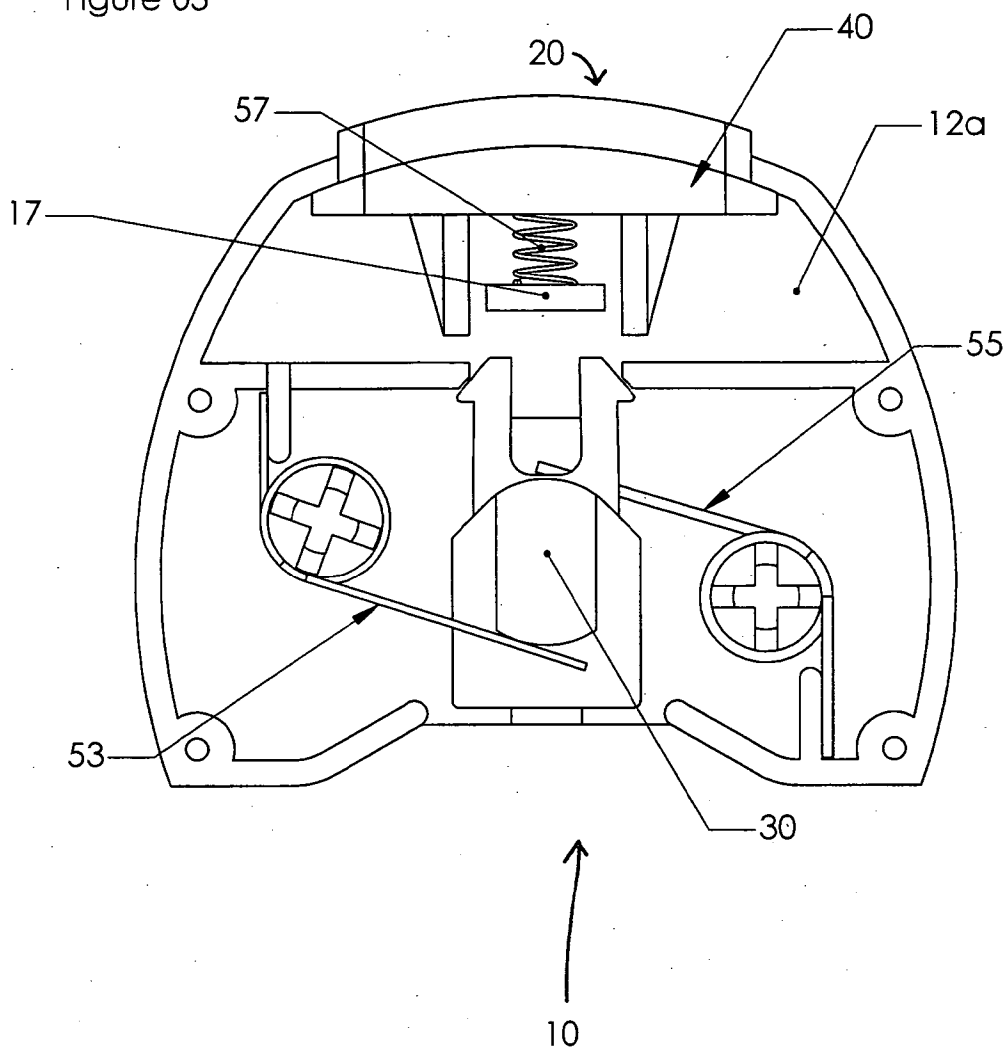
[0036] A multi-use micro-sampling or lancing device having an outer housing, a lancet holder that engages a lancet and constrains the lancet along a controlled and pre-defined path of travel during the lancing stroke, and a drive mechanism with a pair of opposed torsion springs working in tandem to drive and return the lancet holder through its lancing stroke.



Step_00
Uncapped / No Lancet

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SAMPLING DEVICE"
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ATTY TEL: 770.984.2300
ATTY DOCKET No.: 2602.1-190
SHEET 2 OF 9

Figure 03



Step_01
Tabbed Lancet Loaded / Unit Set Position

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SHEET 3 OF 9

Figure 04

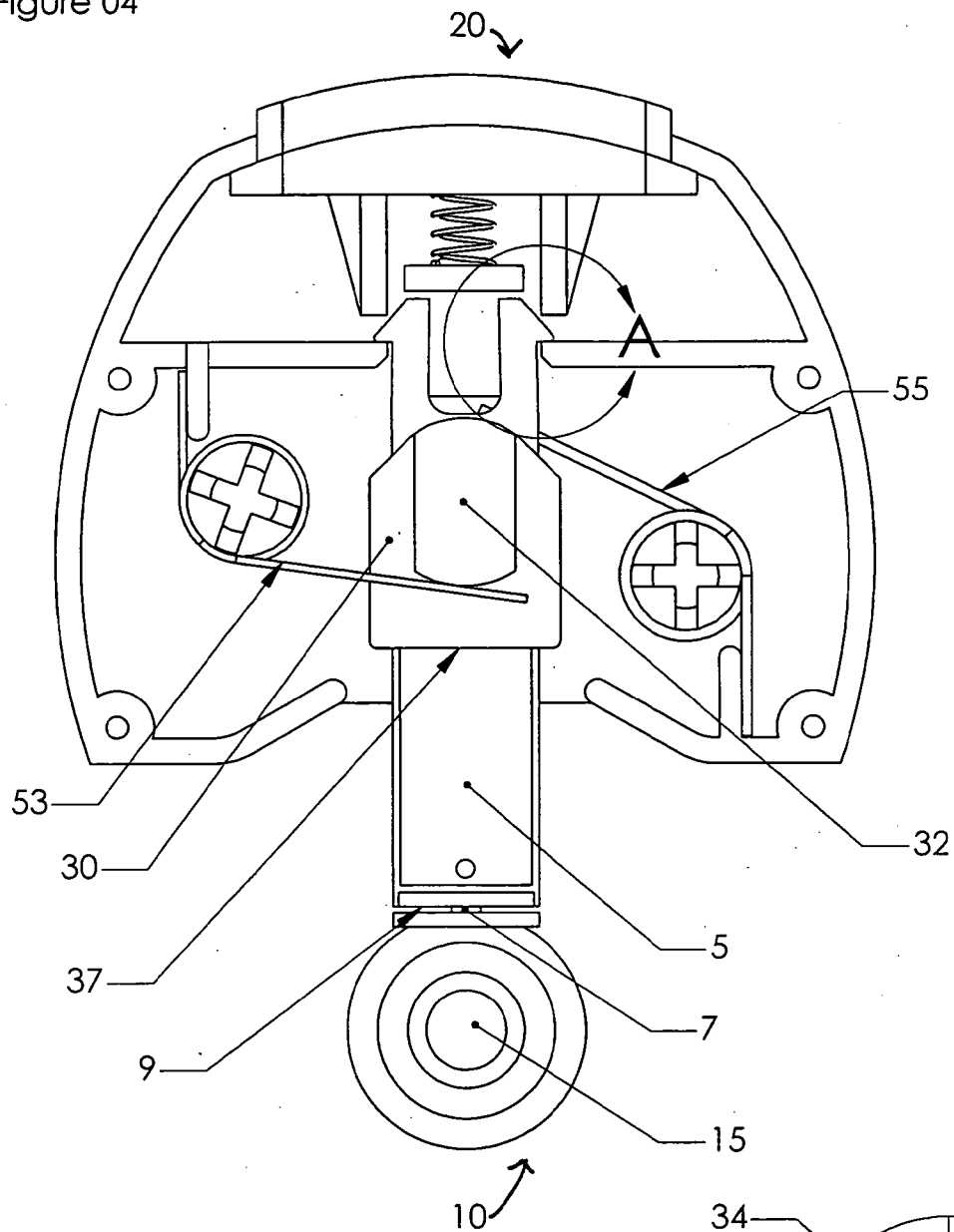
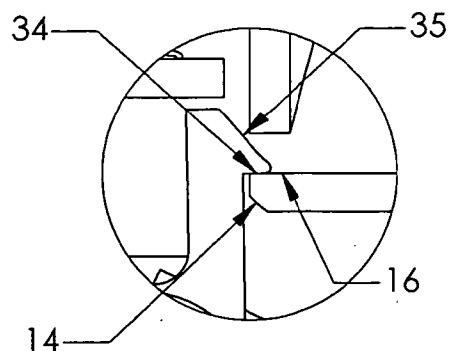
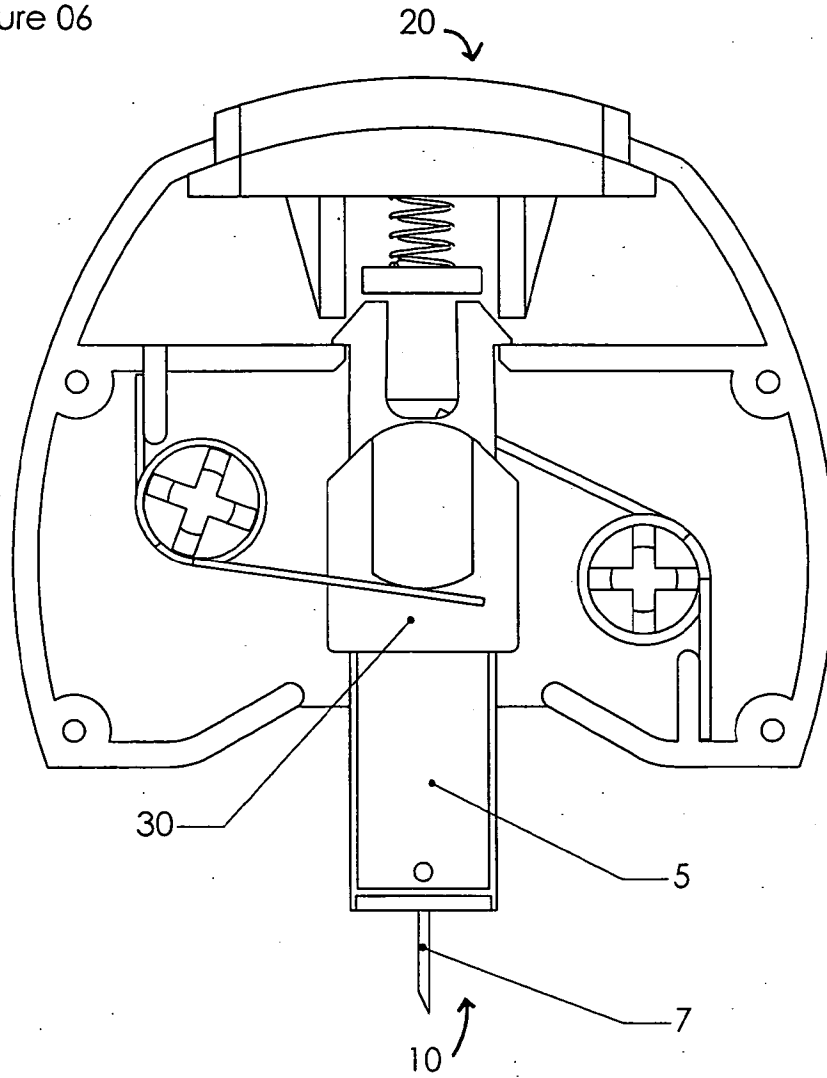


Figure 05



DETAIL A
SCALE 6:1

Figure 06

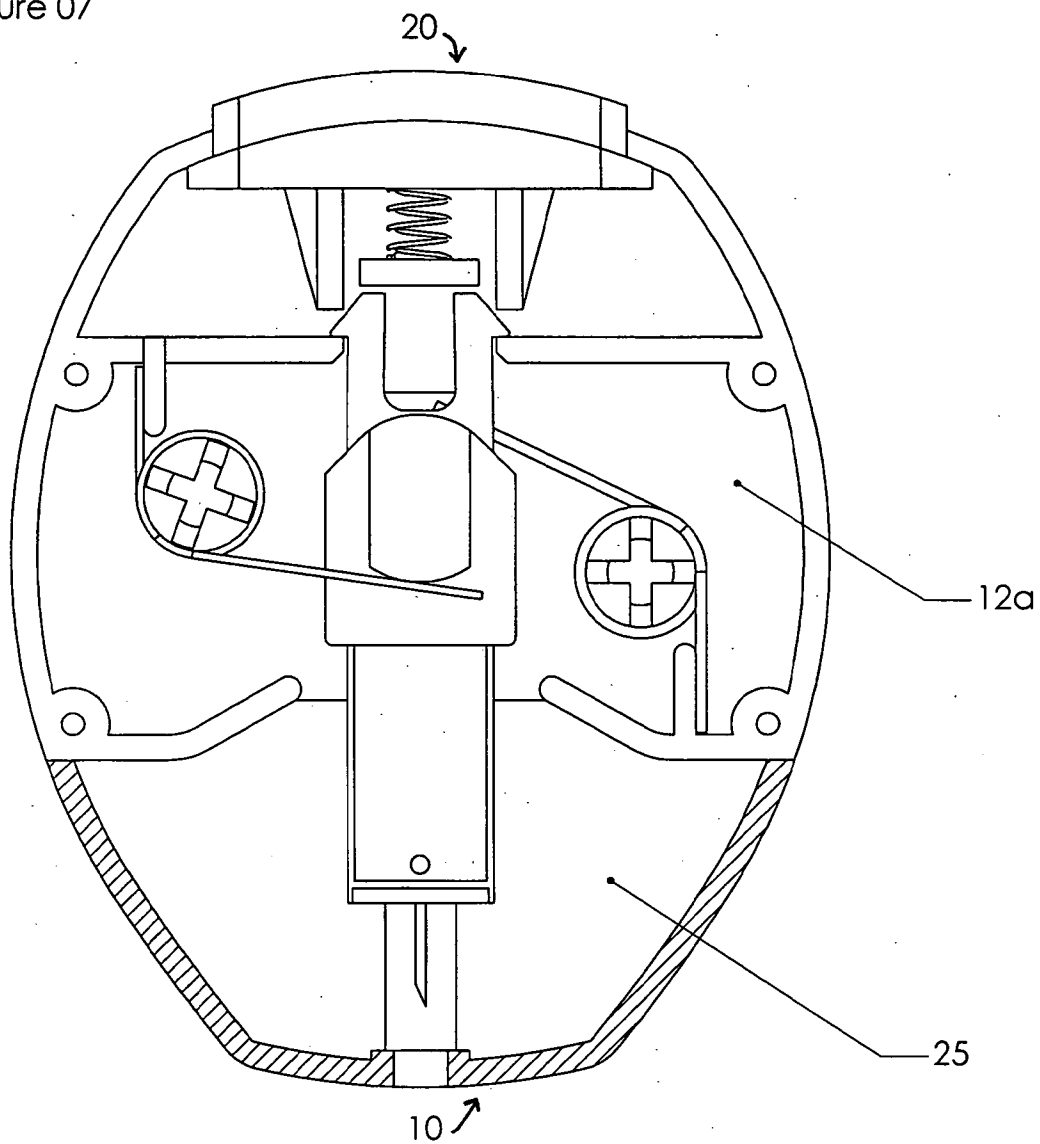


(15)

Step_03
Unit Cap Reinstallation

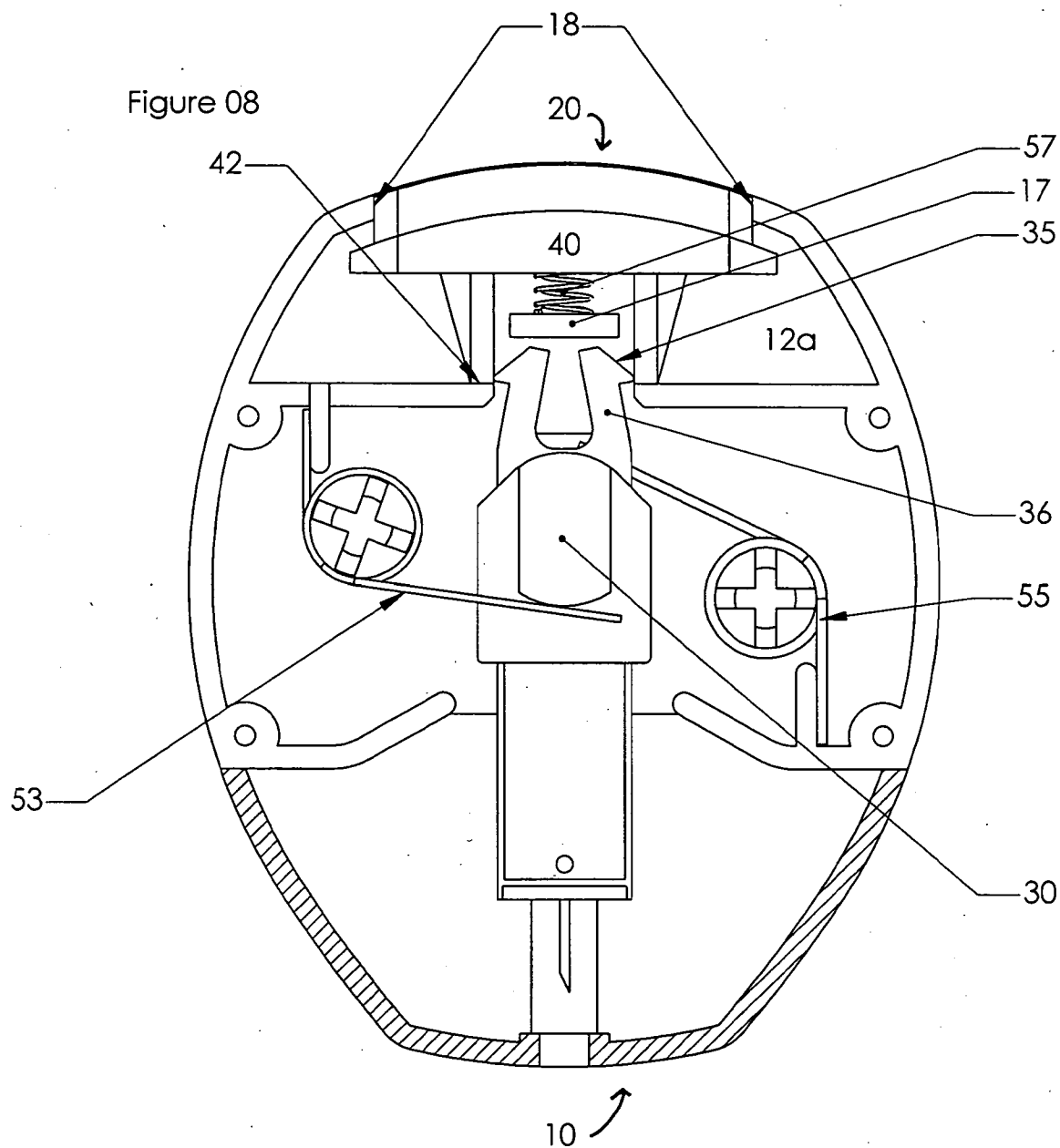
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SHEET 5 OF 9

Figure 07



Step_04:
Fire Button Actuation

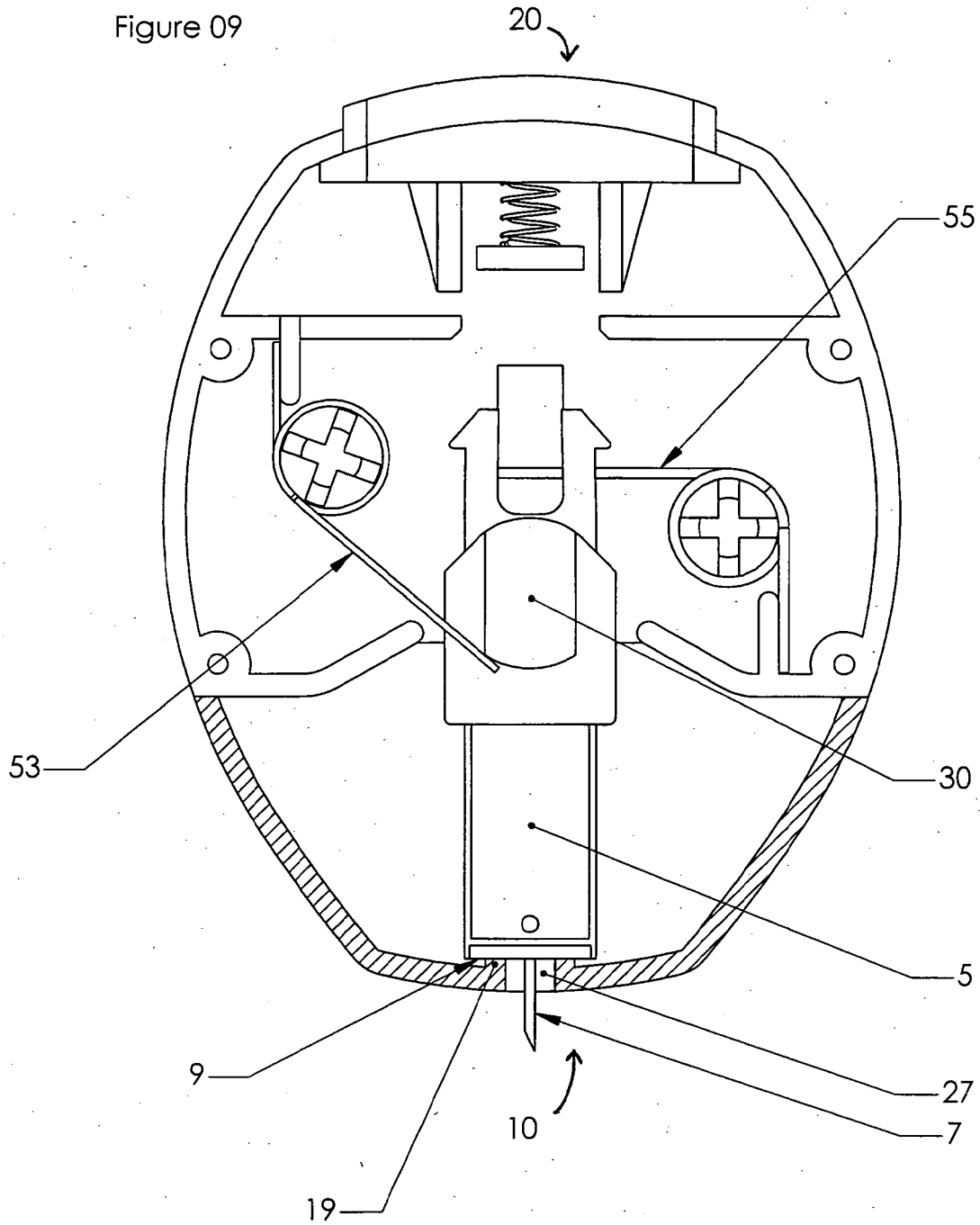
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SHEET 6 OF 9



Step_05
PUNCTURE POSITION

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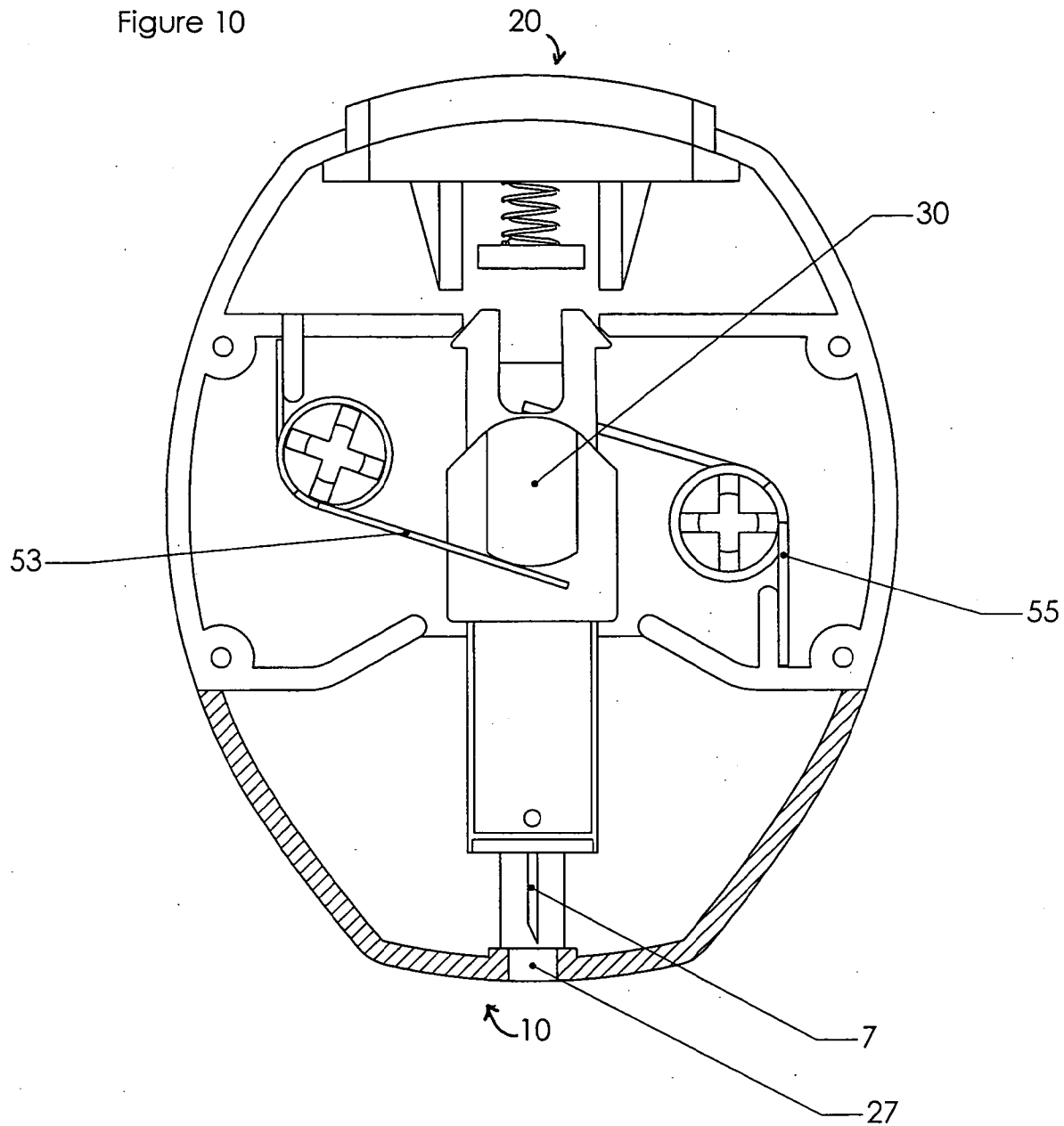
Figure 09



Step_06
POST PUNCTURE REST POSITION

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SHEET 8 OF 9

Figure 10



ALTERNATE EMBODIMENT

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SHEET 9 OF 9

Figure 11

